



EXHIBIT B

ENDONET.023CP3

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: George M. Johnson, et al.	Group Art Unit 3736
Appl. No.	: 09/702,002	
Filed	: October 30, 2000	
For	: METHOD AND DEVICE FOR TREATING GASTROESOPHAGEAL REFLUX DISEASE	
Examiner	: Unknown	

PETITION TO CORRECT INVENTORSHIP UNDER 37 C.F.R. § 1.48(a)

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

This is a petition under 37 C.F.R. § 1.48(a) to correct inventorship in U.S. Patent Application No. 09/702,002, filed on October 30, 2000. The application, as filed, unintentionally omitted one inventor, Philip J. Simpson. The correct inventors in this application are George M. Johnson, John T. Kilcoyne, Ross Tsukashima, Matthew T. Yurek, Scott Harris, and Philip J. Simpson.

Thus, the following inventor should be ADDED to the patent application:

Name:	Philip J. Simpson
Residence:	3185 Pioneer Place, Escondido, CA 92025
Citizenship:	U.S.A.

Accompanying this petition are the following documents: 1) a statement of lack of deceptive intention on the part of Philip J. Simpson; 2) a declaration by the actual inventors as

Appl. No. : 09/702,002
Filed : October 30, 2000

required by 37 C.F.R. § 1.63; 3) the processing fee set forth in 37 C.F.R. § 1.17(i); and 4) the written consent of the assignee, Endonetics, Inc.

Accordingly, it is requested that this Petition be GRANTED and the inventorship of the patent application be corrected.

Please charge any additional fees or credit overpayment to Deposit Account No. 11-1410.

If there are any questions regarding this petition, please contact the undersigned attorney at (949) 760-0404.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 12/11/04

By: James W. Hill
James W. Hill, M.D.
Registration No. 46,396
Attorney of Record
620 Newport Center Drive
Sixteenth Floor
Newport Beach, CA 92660

H:\DOCS\JZH\ZH-2806.DOC/dmg
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ENDONET.023CP3



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : George M. Johnson, et al.

Group Art Unit 3736

Appl. No. : 09/702,002

Filed : October 30, 2000

For : METHOD AND DEVICE FOR
TREATING GASTROESOPHAGEAL
REFLUX DISEASE

Examiner : Unknown

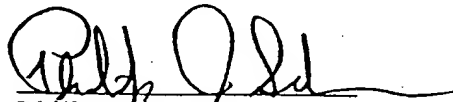
**STATEMENT BY PHILIP SIMPSON
TO CORRECT INVENTORSHIP UNDER 37 C.F.R. § 1.48(a)**

I, Philip J. Simpson, am a United States citizen residing at 3185 Pioneer Place, Escondido, CA 92025. I should be a named inventor in U.S. Patent Application No. 09/702,002, filed on October 30, 2000. I was omitted as an inventor unintentionally, through no deceptive intention on my part.

I now desire to correct inventorship pursuant to 37 C.F.R. § 1.48(a). The correct inventors in this case are George M. Johnson, John T. Kilcoyne, Ross Tsukashima, Matthew T. Yurek, Scott Harris, and Philip J. Simpson.

I have assigned all my interest in this patent application and this invention to Endonetics, Inc., a California corporation located at 11100 Roselle Street, San Diego, CA 92121

Respectfully submitted,


Philip J. Simpson

**DECLARATION - USA PATENT APPLICATION**

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name;

I believe I am an original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled METHOD AND DEVICE FOR TREATING GASTROESOPHAGEAL REFLUX DISEASE; the specification of which was filed on October 30, 2000 as Application Serial No. 09/702,002.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above;

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56;

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) listed below, and insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code § 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56, which became available between the filing date of the prior application and the national or PCT international filing date of this application:

Prior U.S.A. Application

Application No.: 09/287,607

Filing Date: 04/07/99

Status: Issued

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful, false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of first inventor: **GEORGE M. JOHNSON**

Inventor's signature

Date

11/7/01

Residence: 1841 Derby Drive, Santa Ana, CA 92705

Citizenship: United States

Post Office Address: Same as above

Full name of second inventor: JOHN T. KILCOYNE

Inventor's signature 


Date 11/06/01

Residence: ~~5265 Caminito Exquisito~~, San Diego, CA 92130

Citizenship: United States

Post Office Address: Same as above

Full name of third inventor: ROSS TSUKASHIMA

Inventor's signature 

Date 11/7/01

Residence: 11257 Willow Wood Drive, San Diego, CA 92127

Citizenship: United States

Post Office Address: Same as above

Full name of fourth inventor: MATTHEW T. YUREK

Inventor's signature 

Date 11/7/01

Residence: 12957 La Tortola, San Diego, CA 92129

Citizenship: United States

Post Office Address: Same as above

Full name of fifth inventor: SCOTT HARRIS

Inventor's signature 

Date Nov 07, 2001


Residence: 3622 Oliphant Street, San Diego, CA 92016

Citizenship: United States

Post Office Address: Same as above

Full name of sixth inventor: PHILIP SIMPSON

Inventor's signature



Date

11/07/01

Residence: 3185 Pioneer Place, Escondido, CA 92025

Citizenship: United States

Post Office Address: Same as above

Send Correspondence To:

KNOBBE, MARTENS, OLSON & BEAR, LLP

Customer No. 20,995

ENDONET.023073



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : George M. Johnson, et al.

Group Art Unit 3736

Appl. No. : 09/702,002

Filed : October 30, 2000

For : METHOD AND DEVICE FOR
TREATING GASTROESOPHAGEAL
REFLUX DISEASE

Examiner : Unknown


**WRITTEN CONSENT OF ASSIGNEE
IN SUPPORT OF PETITION FOR CORRECTION OF INVENTORSHIP
UNDER 37 C.F.R. §1.48(a)**

Endonetics, Inc., a California corporation located at 11100 Roselle Street, San Diego, CA 92121, is the owner and assignee of record of the above-identified patent application. A copy of the assignment reflecting the chain of title to Endonetics, Inc. is attached hereto.

The assignee is aware of the error with respect to inventorship of the above-identified patent application. The assignee hereby consents to the requested correction of inventorship which adds Philip J. Simpson as a joint inventor of the above-referenced patent.

Respectfully submitted,

ENDONETICS, INC.


John T. Kilcoyne
President & Chief Executive Officer

UTILITY/DESIGN PATENT

DATE: 12-11-01

(amend/final amend)

DATE OF O.A.: _____

Rec'd in the U.S.P.T.O. on the date stamped hereon via Certificate of Mail:

Atty Dkt # Enbnd 02303 A/N 09/102,002

Filed: 10-30-00

Ext: Unknown

Atty: 524

Art Unit: 3736

Applicant(s): G. Johnson et al.

Title: Method & Device for Treating Gastroesophageal Reflux...

VERIFIED BY: Asst: Danni G.

Quality Control: _____

☐ Transmittal Sheet in dupl.

☐ Amendment in _____ pgs.

☐ _____ Mo. Ext. of Time in dupl.

☐ Small Entity Statement(s) _____

☐ Req. for Drawing Changes marked in RED ☒ Submission of Formal Drawings

_____ pgs of Drawings

Transmittal

☐ Information Disclosure Statement;

☐ _____ pgs of Formal Drawings

PTO-1449 w/ _____ Refs.

☐ _____ Check for Amendment

☐ Issue Fee Transmittal in dupl.

☐ _____ Issue Fee Soft Copies

☒ Petition - correct Inventor Mark G. G.

☒ Written consent of Assignee - HP

☒ Stmt. of P. Simpson - 1 pg

☒ \$13000 petition Fee

☒ Declaration Inventor & co.

☒ Return Postcard & Assignment

Client Code: ENDONET.023CP3



**RECORDATION FORM COVER SHEET
PATENTS ONLY**

TO THE ASSISTANT COMMISSIONER FOR PATENTS: Please record the attached original documents or copy thereof.

1. Name of conveying party

Philip J. Simpson

Additional name(s) of conveying party(ies) attached?

() Yes (X) No

2. Name and address of receiving party:

Name: ENDONETICS, INC.

Internal Address:

Street Address: 11100 Roselle Street

City: San Diego State: CA ZIP: 92121

Additional name(s) of receiving party(ies) attached?

() Yes (X) No

3. Nature of conveyance:

- (X) Assignment
() Merger
() Security Agreement
() Change of Name
() Other:

Execution Date: October 30, 2001

4. Application number(s) or Patent number(s):

() Application(s) filed herewith Execution Date(s):

(X) Patent Application No.: 09/702,002

Filing Date: October 30, 2000

() Patent No.:

Issue Date:

Additional numbers attached? () Yes (X) No

5. Name and address of party to whom correspondence concerning document should be mailed:

Name: James W. Hill, M.D.
KNOBBE, MARTENS, OLSON & BEAR, LLP
Customer No. 20,995

Internal Address: Sixteenth Floor

Street Address: 620 Newport Center Drive

City: Newport Beach State: CA ZIP: 92660

Attorney's Docket No.: ENDONET.023CP3

7. Total fee (37 CFR 1.21(h)): \$40.00

(X) Enclosed

(X) Authorized to be charged to deposit account if any additional fees are required, or to credit any overpayment

8. Deposit account number: 11-1410

Please charge this account for any additional fees which may be required, or credit any overpayment to this account.

6. Total number of applications and patents involved: 1

9. Statement and signature.

To the best of my knowledge and belief, the foregoing information is true and correct, and any attached copy is a true copy of the original document.

James W. Hill, M.D.

Name of Person Signing

Signature

Date

46,396

Registration No.

Total number of pages including cover sheet, attachments and document: 2

Mail documents to be recorded with required cover sheet information to:

U.S. Patent and Trademark Office
Attn: Assignment Division
Crystal Gateway-4
1213 Jefferson Davis Highway, Suite 320
Arlington, VA 22202

ASSIGNMENT

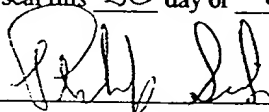
WHEREAS, I, ^{PHILIP PJS} Philip Simpson, a United States citizen, residing at 3185 Pioneer Place, Escondido, CA 92025, have invented certain new and useful improvements in a METHOD AND DEVICE FOR TREATING GASTROESOPHAGEAL REFLUX DISEASE for which an application for U.S. Letters Patent has been filed October 30, 2000, U.S. Patent Application No. 09/702,002;

AND WHEREAS, ENDONETICS, INC. (hereinafter "ASSIGNEE"), a California Corporation, with its principal place of business at 11100 Roselle Street, San Diego, CA 92121, desires to acquire the entire right, title, and interest in and to the said improvements and the said Application:

NOW, THEREFORE, in consideration of the sum of One Dollar (\$1.00) to me in hand paid, and other good and valuable consideration, the receipt of which is hereby acknowledged, I, the said inventor, do hereby acknowledge that I have sold, assigned, transferred and set over, and by these presents do hereby sell, assign, transfer and set over, unto the said ASSIGNEE, his successors, legal representatives and assigns, any and all right, title, and interest I do or may own throughout the world in, to and under the said improvements, and the said application and all provisional applications relating thereto, and all divisions, renewals and continuations thereof, and all Letters Patent of the United States which may be granted thereon and all reissues and extensions thereof, and all rights of priority under International Conventions and applications for Letters Patent which may hereafter be filed for said improvements in any country or countries foreign to the United States, and all Letters Patent which may be granted for said improvements in any country or countries foreign to the United States and all extensions, renewals and reissues thereof; and I hereby authorize and request the Commissioner of Patents of the United States, and any Official of any country or countries foreign to the United States, whose duty it is to issue patents on applications as aforesaid, to issue all Letters Patent for said improvements to the said ASSIGNEE, his successors, legal representatives and assigns, in accordance with the terms of this instrument.

AND I HEREBY covenant and agree that I will communicate to the said ASSIGNEE, his successors, legal representatives and assigns, any facts known to me respecting said improvements, and testify in any legal proceeding, sign all lawful papers, execute all divisional, continuing and reissue applications, make all rightful oaths and generally do everything possible to aid the said ASSIGNEE, his successors, legal representatives and assigns, to obtain and enforce proper patent protection for said improvements in all countries.

IN TESTIMONY WHEREOF, I hereunto set my hand and seal this 30 day of OCTOBER, 2000.



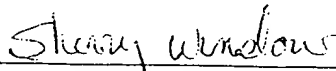
Philip Simpson
PHILIP PJS

STATE OF California }
COUNTY OF San Diego } ss.

On October 30, 2000 before me, Sherry Winslow, personally appeared Phil Simpson personally known to me (or proved to me on the basis of satisfactory evidence) to be the person(s) whose name(s) is/are subscribed to the within instrument, and acknowledged to me that he executed the same in his authorized capacity(ies), and that by his signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

WITNESS my hand and official seal.

[SEAL]



Notary Signature

H:\DOCS\UJ\HJ\H-2723.DXX\dmg 102601



UTILITY/DESIGN PATENT

(miscellaneous)

Date: 12-11-01

Date of O.A.: _____

Rec'd in the U.S.P.T.O. on the date stamped hereon via Certificate of Mail:

Atty. Dkt. # Endonch. 623CP3 A/N: 702,002 Filed: 10-30-00

Pat. # _____ Issued: _____ Atty: J2H

Exr: Unknown Art Unit: 3736 Batch: _____ Re-Exam # _____

Title: Method & Device for Treating Applicant: G. Johnson et al

VERIFIED BY: Asst: Danni G. Quality Control: _____

☒ Assignment & Recordation Fee: 12985

☒ Recording fee 1400

☐ _____ 2001 DEC 14 PM 1:06

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☒ Return Postcard



UNITED STATES
PATENT AND
TRADEMARK OFFICE

FEBRUARY 05, 2002

PTAS
KNOBBE, MARTENS, OLSON & BEAR, LLP
JAMES W. HILL, M.D.
620 NEWPORT CENTER DRIVE
SIXTEENTH FLOOR
NEWPORT BEACH, CA 92660

Under Secretary of Commerce For Intellectual Property and
Director of the United States Patent and Trademark Office
Washington, DC 20231
www.uspto.gov



101918480A

UNITED STATES PATENT AND TRADEMARK OFFICE
NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT

THE ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT DIVISION OF THE U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE MICROFILM COPY IS AVAILABLE AT THE ASSIGNMENT SEARCH ROOM ON THE REEL AND FRAME NUMBER REFERENCED BELOW.

PLEASE REVIEW ALL INFORMATION CONTAINED ON THIS NOTICE. THE INFORMATION CONTAINED ON THIS RECORDATION NOTICE REFLECTS THE DATA PRESENT IN THE PATENT AND TRADEMARK ASSIGNMENT SYSTEM. IF YOU SHOULD FIND ANY ERRORS OR HAVE QUESTIONS CONCERNING THIS NOTICE, YOU MAY CONTACT THE EMPLOYEE WHOSE NAME APPEARS ON THIS NOTICE AT 703-308-9723. PLEASE SEND REQUEST FOR CORRECTION TO: U.S. PATENT AND TRADEMARK OFFICE, ASSIGNMENT DIVISION, BOX ASSIGNMENTS, CG-4, 1213 JEFFERSON DAVIS HWY, SUITE 320, WASHINGTON, D.C. 20231.

RECORDATION DATE: 12/14/2001

REEL/FRAME: 012362/0085
NUMBER OF PAGES: 2

BRIEF: ASSIGNMENT OF ASSIGNOR'S INTEREST (SEE DOCUMENT FOR DETAILS).

ASSIGNOR:

SIMPSON, PHILIP J.

DOC DATE: 10/30/2001

ASSIGNEE:

ENDONETICS, INC.
11100 ROSELLE STREET
SAN DIEGO, CALIFORNIA 92121

SERIAL NUMBER: 09702002
PATENT NUMBER:

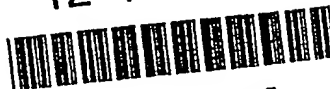
FILING DATE: 10/30/2000
ISSUE DATE:

JOANN STEWART, EXAMINER
ASSIGNMENT DIVISION
OFFICE OF PUBLIC RECORDS

Client Code: ENDONET.023CP3

12-14-2001

12-17-2001



101918480

TO THE ASSISTANT COMMISSIONER FOR

documents or copy thereof.

1. Name of conveying party

Philip J. Simpson

Additional name(s) of conveying party(ies) attached?

() Yes (X) No

2. Name and address of receiving party:

Name: ENDONETICS, INC.

Internal Address:

Street Address: 11100 Roselle Street

City: San Diego State: CA ZIP: 92121

Additional name(s) of receiving party(ies) attached?

() Yes (X) No

3. Nature of conveyance:

- (X) Assignment
() Merger
() Security Agreement
() Change of Name
() Other:

Execution Date: October 30, 2001

4. Application number(s) or Patent number(s):

() Application(s) filed herewith Execution Date(s):

(X) Patent Application No.: 09/702,002

Filing Date: October 30, 2000

() Patent No.:

Issue Date:

Additional numbers attached? () Yes (X) No

5. Name and address of party to whom correspondence concerning document should be mailed:

Name: James W. Hill, M.D.
KNOBBE, MARTENS, OLSON & BEAR, LLP
Customer No. 20,995

Internal Address: Sixteenth Floor

Street Address: 620 Newport Center Drive

City: Newport Beach State: CA ZIP: 92660

Attorney's Docket No.: ENDONET.023CP3

7. Total fee (37 CFR 1.21(h)): \$40.00

(X) Enclosed

(X) Authorized to be charged to deposit account if any additional fees are required, or to credit any overpayment

8. Deposit account number: 11-1410

Please charge this account for any additional fees which may be required, or credit any overpayment to this account.

6. Total number of applications and patents involved: 1

9. Statement and signature.

To the best of my knowledge and belief, the foregoing information is true and correct, and any attached copy is a true copy of the original document.

James W. Hill, M.D.
Name of Person Signing

Signature

Date

46,396

Registration No.

Total number of pages including cover sheet, attachments and document: 2

Mail documents to be recorded with required cover sheet information to:

12/17/2001 6T0H11 00000005 09702002

01 FC:581

40.00

U.S. Patent and Trademark Office
Attn: Assignment Division
Crystal Gateway-4
1213 Jefferson Davis Highway, Suite 320
Arlington, VA 22202

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Application No.: 09/702,002
Filing Date: October 30, 2000

PATENT
Client Code: ENDONET.023CP3
Page 1

ASSIGNMENT

WHEREAS, I, ^{PHILIP JS} Phillip Simpson, a United States citizen, residing at 3185 Pioneer Place, Escondido, CA 92025, have invented certain new and useful improvements in a METHOD AND DEVICE FOR TREATING GASTROESOPHAGEAL REFLUX DISEASE for which an application for U.S. Letters Patent has been filed October 30, 2000, U.S. Patent Application No. 09/702,002;

AND WHEREAS, ENDONETICS, INC. (hereinafter "ASSIGNEE"), a California Corporation, with its principal place of business at 11100 Roselle Street, San Diego, CA 92121, desires to acquire the entire right, title, and interest in and to the said improvements and the said Application:

NOW, THEREFORE, in consideration of the sum of One Dollar (\$1.00) to me in hand paid, and other good and valuable consideration, the receipt of which is hereby acknowledged, I, the said inventor, do hereby acknowledge that I have sold, assigned, transferred and set over, and by these presents do hereby sell, assign, transfer and set over, unto the said ASSIGNEE, his successors, legal representatives and assigns, any and all right, title, and interest I do or may own throughout the world in, to and under the said improvements, and the said application and all provisional applications relating thereto, and all divisions, renewals and continuations thereof, and all Letters Patent of the United States which may be granted thereon and all reissues and extensions thereof, and all rights of priority under International Conventions and applications for Letters Patent which may hereafter be filed for said improvements in any country or countries foreign to the United States, and all Letters Patent which may be granted for said improvements in any country or countries foreign to the United States and all extensions, renewals and reissues thereof; and I hereby authorize and request the Commissioner of Patents of the United States, and any Official of any country or countries foreign to the United States, whose duty it is to issue patents on applications as aforesaid, to issue all Letters Patent for said improvements to the said ASSIGNEE, his successors, legal representatives and assigns, in accordance with the terms of this instrument.

AND I HEREBY covenant and agree that I will communicate to the said ASSIGNEE, his successors, legal representatives and assigns, any facts known to me respecting said improvements, and testify in any legal proceeding, sign all lawful papers, execute all divisional, continuing and reissue applications, make all rightful oaths and generally do everything possible to aid the said ASSIGNEE, his successors, legal representatives and assigns, to obtain and enforce proper patent protection for said improvements in all countries.

IN TESTIMONY WHEREOF, I hereunto set my hand and seal this 30 day of OCTOBER, 2001.

[Signature]

Phillip Simpson
PHILIP JS

STATE OF California }
COUNTY OF San Diego } ss.

On October 30, 2001 before me, Sherry Winslow, personally appeared Phil Simpson personally known to me (or proved to me on the basis of satisfactory evidence) to be the person(s) whose name(s) is/are subscribed to the within instrument, and acknowledged to me that he executed the same in his authorized capacity(ies), and that by his signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

WITNESS my hand and official seal.

[SEAL]

[Signature]

Notary Signature

H:\DOCS\JZH\JZH-2723.DOC\dmg 102601

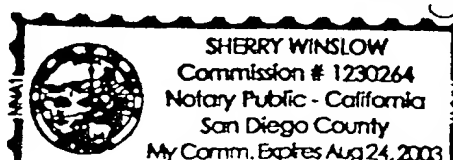




EXHIBIT C

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20521
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/702,002	10/30/2000	George M. Johnson	BQD-093.01	7813

27581 7590 07/31/2002
MEDTRONIC, INC.
710 MEDTRONIC PARKWAY NE
MS-LC340
MINNEAPOLIS, MN 55432-5604

EXAMINER

VENIAMINOV, NIKITA R

ART UNIT PAPER NUMBER

3736

DATE MAILED: 07/31/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No

09/702,002

Applicant(s)

JOHNSON ET AL.

Examiner

Krista R. Veniaminov

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of.
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s): 4, 7, 8, 11, 12
- 4) ☐ Interview Summary (PTO-413) Paper No(s): _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Inventorship

1. In view of the papers No. 9 and 10 filed on January 08, 2002, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48 (a). The inventorship of this application has been changed by deleting the inventor's named Gerard Von Hoffmann (see paper # 10) and correcting the named inventors (see paper # 9). The correct inventors in this application are George M. Johnson, John T. Kilcoyne, Ross Tsukashima, Matthew T. Yurek, Scott Harris, and adding the inventor's name Philip J. Simpson.
2. The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1-11, 14-16, 19, 20, 22, 23, 27, 28, 30, 32 and 34-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Silverman et al. ('063) cited by Applicant. Silverman et al. ('063) teach a method of implanting a bulking device beneath mucosa in the lower esophagus comprising the steps of: puncturing the mucosa with a device having a first cross sectional area (see Figure 2); creating a pocket beneath the mucosa by introducing a volume of fluid, wherein the fluid comprises saline or contrast media (see column 11, lines 10-29) within the range of from about 0.5 cc to about 5 cc of fluid beneath the mucosa (see column 15, lines 33-39), wherein the introducing a volume of fluid is accomplished using an

injection needle, wherein the needle is within the range of from about 18 gauge to about 30 gauge (see column 5, lines 16-21), and in communication with the puncture; enlarging the puncture; and introducing a hydrogel, which is inherently expandable in response to exposure to fluid, bulking device (see column 9, lines 54-66) through the puncture and into the pocket (see Figures 7 and 8; column 15, lines 23-39), wherein the bulking device is expandable from an introduction cross sectional area to an enlarged cross sectional area, and the introduction cross sectional area is greater than the first cross sectional area (see figures 7 and 8; and column 19, lines 31-34). Further, Silverman et al. ('063) teach a method of implanting the bulking device, wherein the puncture enlarging step comprises introducing a dilator (balloon) through the puncture (see column 19, lines 31-34); and advancing a tube through the enlarged puncture and introducing the bulking device through the tube (see column 4, lines 21-31). Also, Silverman et al. ('063) teach a method of removing the bulking device from the pocket, which is accomplished by creating (establishing) a passageway through tissue (mucosa) to the bulking device, by introducing a solvent DMSO to dissolve the bulking device, by using a sharpened instrument (needle) (see column 19, lines 20-34); by using an endoscope (see column 4, lines 17-30). A step of locating the bulking device is an inherent step of the method of explanting said bulking device.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 17, 18, 21, 24-26, 29, 31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverman et al. ('063) cited by Applicant as applied to claims 14, 15, 19, 20 and 27 above. With regard to claims 17 and 18 Silverman et al. ('063) teach methods of implanting and explanting a bulking device beneath mucosa in the lower esophagus, as described in paragraph 5 above, but they do not teach a method of implanting a bulking device, wherein the bulking device has a diameter prior to implantation within the range of from about 0.2 mm to about 5 mm, and has a cross section prior to implantation of no more than about 2.5 mm. It would have been obvious to one of ordinary skill in the art at the time of the invention to determine through routine experimentation an appropriate diameter and cross section for implementing the bulking device prior to implantation within the range of diameters and cross sections Applicant provides in the claims. With regard to claims 21, 24-26, 29 and 31-33 Silverman et al. ('063) teach methods of implanting and explanting a bulking device beneath mucosa in the lower esophagus, as described in paragraph 5 above, but they do not teach a method of explanting or removing the bulking device using suction, utilizing a laser, using

an energy source, cutting the bulking device into pieces, using a mechanical explanting tool, using an RF electrode, pushing the bulking device through the passage. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to use suction, a laser, a energy source, cutting, a mechanical explanting tool, an RF electrode, or pushing the bulking device through the passage for the solvent-based extraction of Silverman et al ('063), since it has generally been held to be within the skill level of the art to substitute alternative ways for explanting implants from the tissues or organs.

8. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverman et al. ('063) cited by Applicant as applied to claims 1 and 11 above, in view of Schiff (US 4,473,067). Silverman et al. ('063) teach methods of implanting and explanting a bulking device beneath mucosa in the lower esophagus, as described in paragraph 5 above, but they do not teach a method of implanting a bulking device, wherein the dilator removably carries an introducer sheath, and the steps of removing the dilator from the introducer sheath and introducing the bulking device through the introducer sheath and into the pocket. However, Schiff ('067) teaches a dilator (balloon catheter) inserted into an introducer sheath (see abstract and Figure 5), steps of introducing the sheath with the dilator into the body of the patient (see column 2, lines 26-31), and steps of removing the dilator from the introducer sheath, wherein the portion of the sheath within the artery simplifies removal of the dilator (balloon) through the sheath rather than pulling the dilator (balloon catheter) (see column 2, lines

26-31 and column 6, lines 6-27). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method steps of Silverman et al. ('063) by including an introducer sheath as taught by Schiff ('067), since Schiff ('067) teaches an introducer sheath, which simplifies removal of the dilator (balloon) through the sheath rather than pulling the dilator (balloon catheter).

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bacich et al. ('889); Kaplan et al. ('563); Murphy-Chutorian et al. ('577); Winkler A.R., McClenathan D.T., Borger J.A., Ahmed N. "Retrograde esophagoscopy for foreign body removal". May 1989; Journal of Pediatric Gastroenterology and Nutrition; 8(4); pp 536-40 (Abstract only), and Bertoni G, Pacchione D, Sassatelli R., Ricci E., Mortilla M.G., Gumina C. "A new protector device for safe endoscopic removal of sharp gastroesophageal foreign bodies in infants", May 1993; J Pediat Gastroent Nutr; 1(4); pp 393-6 (Abstract only).

Art Unit: 3736

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikita R Veniaminov whose telephone number is (703) 605-0210. The examiner can normally be reached on Monday-Friday 8 A.M.-5 P.M..

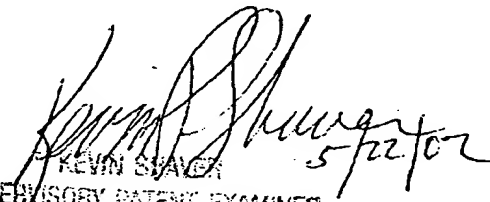
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eric F Winakur can be reached on (703) 308-3940. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0758 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Nikita R Veniaminov
Examiner
Art Unit 3736

April 26, 2002



KEVIN STAGER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700
5/22/02

EXHIBIT D



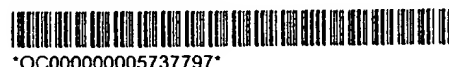
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APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	DRAWINGS	TOT CLAIMS	IND CLAIMS
09/702,002	10/30/2000	3736	0	ENDONET.023CP3	12	37	4

20995
KNOBBE MARTENS OLSON & BEAR LLP
620 NEWPORT CENTER DRIVE
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FILING RECEIPT



OC000000005737797

Date Mailed: 02/06/2001

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Customer Service Center. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the PTO processes the reply to the Notice, the PTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

Gerard von Hoffmann, Residence Not Provided;

Continuing Data as Claimed by Applicant

THIS APPLICATION IS A CIP OF 09/524,478 03/13/2000
WHICH IS A CIP OF 09/287,607 04/07/1999 PAT 6,098,629

Foreign Applications

If Required, Foreign Filing License Granted 02/05/2001

** SMALL ENTITY **

Title

Method and device for treating gastroesophageal reflux disease

Preliminary Class

128

Data entry by : TYSON, LASHONNAH

Team : OIPE

Date: 02/06/2001



NO DATES DOCKETED^{5N}
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